UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA, ex rel. ELAINE GEORGE, Plaintiffs, v. BOSTON SCIENTIFIC CORP. and GUIDANT CORP. Defendants	Civil Action No. H-07-2467 (J. Rosenthal) **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730**

UNITED STATES' STATEMENT OF INTEREST
IN RESPONSE TO DEFENDANT'S MOTION TO DISMISS
PLAINTIFF'S FIRST AMENDED COMPLAINT

The United States, real party in interest in this action, submits this Statement of Interest pursuant to 28 U.S.C. § 517 to respond to certain arguments that Defendants Boston Scientific Corporation and Guidant Corporation make in their Motion to Dismiss Relator's First Amended Complaint. The United States remains the real party in interest in this matter, even where it has not intervened in the action. United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 231 (1st Cir. 2004). The False Claims Act (FCA), 31 U.S.C. § 3729 et seq., is the United States' primary tool used to redress fraud on the government. Thus, the United States has a keen interest in the development of the law in this area and in the correct application of the law in this, and similar, cases.

The United States submits this brief to make four points. First, the identification of specific false claims is not an absolute prerequisite to satisfying the particularity requirement of Rule 9(b) in FCA cases. So long as the complaint as a whole is sufficiently particular to strengthen the inference of fraud beyond possibility, a court may conclude that Rule 9(b) is satisfied. Nonetheless, if the Court finds that relator's complaint fails to meet that test and is subject to dismissal under Rule 9(b), then it need not reach the other issues addressed herein. Second, a complaint need not allege that defendants themselves made false statements – defendants may violate section (a)(1) of the FCA by causing a third party to submit an

impermissible claim for reimbursement. Third, section (a)(1) of the FCA does not require a "double falsehood," and with respect to section (a)(1)(B) of the FCA (formerly section (a)(2)), promoting a product off-label may indeed amount to a half truth so as to satisfy the false statement requirement.[1] Fourth, the actions of healthcare professionals are not an intervening force that breaks the chain of legal causation, especially when those actions are the intended consequence of a defendant's alleged fraudulent scheme.

I. FCA Pleading Requirements

Defendants argue that relator's complaint fails to allege fraud with sufficient particularity in that relator has not identified any specific false claims resulting from defendants' alleged conduct. Defs. Brief at 27. The United States takes no position regarding the outcome of the Court's analysis under Rule 9(b). However, the United States notes that to the extent that defendants contend that relator's complaint must fail solely on the ground that it did not identify specific false claims or do so with sufficient particularity, defendants seek to impose too rigid a pleading standard in FCA cases.

As a general matter, the allegation of a specific false claim is not an absolute prerequisite to pleading a viable FCA claim. Although FCA liability attaches to the claim for payment, whether specific claims must be identified for a complaint to satisfy Rule 9(b)'s particularity requirement will depend on the circumstances of each case. See United States ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 192 (5th Cir. 2009) ("That fraudulent bills were presented to the Government is the logical conclusion of the particular allegations in [relator's] complaint even though it does not include exact billing numbers or amounts."); United States ex rel. Lusby v. Rolls-Royce Corp., 570 F.3d 849 (7th Cir. 2009) ("No complaint needs to rule out all possible defenses."); United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 732 (1st Cir. 2007); United

[1] Section 3729 of the FCA was amended in 2009. See Fraud Enforcement and Recovery Act ("FERA"), Pub. L. No. 111-21, 123 Stat. 1617 (2009). Sections (a)(1) and (a)(2) were recodified as Sections (a)(1)(A) and (a)(1)(B), respectively. Section (a)(1)(A) applied to all conduct occurring after the date of enactment, whereas Section (a)(1)(B) applied retroactively. See FERA § 4(f). Therefore, we have used the recodified section numbering for Section (a)(1)(B) throughout this brief.

States ex rel. West v. Ortho-McNeil Pharm., Inc., 2008 WL 435497, at *18 (D. Mass. Feb. 19, 2008). Thus, in off-label cases, where the alleged false claims were submitted not by the defendant, but instead by a third party, a relator "need not allege the details of particular claims, so long as 'the complaint as a whole is sufficiently particular to pass muster under the FCA.'" See Rost, 507 F.3d at 732 (quoting Karvalas, 360 F.3d at 225). Such an analysis is consistent with FCA cases in which courts have found that when a complaint sets forth with particularity allegations of a fraudulent scheme or course of conduct, it is not also necessary to identify specific claims because doing so adds little to the sufficiency of the complaint as a whole. See United States ex rel. Singh v. Bradford Reg'l Med. Ctr., 2006 WL 2642518, at *7 (W.D. Pa. 2006) ("[T]he falsity of the instant claims does not turn on anything unique to any individual claim or that would be revealed from an examination of any claim, but rather the claims 'are false because of the improper financial arrangements between [defendant] and the physicians.'"). In evaluating the sufficiency of a relator's allegations, "the strength of the inference of fraud on the government" may be measured by, for example, factual or statistical evidence tending to show fraud beyond possibility. United States ex rel. West v. Ortho-McNeil Pharm., Inc., 2008 WL 435497, at *18 (D. Mass. Feb. 19, 2008).

If the Court determines that relator has failed to plead his claims with sufficient particularity, it need not address the issues discussed in Sections II through IV of this submission. If the Court does dismiss the case based on Rule 9(b), however, the dismissal should be without prejudice to the United States, as the United States has no role in preparing a relator's complaint and should not be barred from pursuing claims in the future because a relator's complaint failed to pass muster under Rule 9(b). See United States ex rel. Williams v. Bell Helicopter Textron Inc., 417 F.3d 450, 456 (5th Cir. 2005) ("[D]ismissal with prejudice as to the United States was unwarranted where, as here, the relator's claims were dismissed on a Rule 12(b)(6) motion based on a lack of specificity in the complaint as required by Rule 9(b).").

II. Falsity Under the FCA

In their brief, defendants observe that once FDA has cleared or approved a medical device, physicians may use that device for any indication – even indications that are not identified on the device's label. Defs.' Brief at 12. Because physicians can lawfully use medical devices for off-label indications, defendants assert that any claims submitted to federal healthcare programs for such off-label uses cannot be "false." Defs.' Brief at 12-13. This is not accurate. Simply because a physician may lawfully use a device off-label does not mandate that federal healthcare programs cover services involving such off-label uses. See Goodman v. Sullivan , 891 F.2d 449 (2d Cir. 1989) ("Medicare statute does not require coverage for all medically necessary procedures . . . ."); Svidler v. Dept. of Health and Human Servs., 2004 WL 2005781, at *5 (N.D. Cal. Sept. 8, 2004) ("Plaintiff then argues that because she is allowed to prescribe off label uses, Medicare must pay for off label uses. This leap of logic is unwarranted."). Coverage under federal healthcare programs is limited to medical services that are "reasonable and necessary" for the diagnosis or treatment of illness or injury. *See* 42 U.S.C. § 1395y(a)(1)(A) (defining scope of Medicare benefits); 32 C.F.R. 199.4(a)(1)(i) (defining scope of benefits under federal military healthcare plan known as TRICARE). Medical devices that are not cleared or approved by the FDA are considered "investigational" by federal healthcare programs and are not "reasonable and necessary." See 42 C.F.R. § 411.15(o) (excluding Medicare coverage for "experimental or investigational devices"); 32 C.F.R. § 199.4(g)(15) (excluding TRICARE coverage for "unproven drugs, devices, and medical treatments or procedures"). When a medical device is cleared or approved for a particular intended use, federal healthcare programs still may deny coverage for procedures involving that medical device, including denying coverage for certain off-label uses. See Svidler, 2004 WL 2005781 (holding that medical procedure involving the use of an FDA-cleared medical device for an off-label use was experimental and not covered under Medicare); TRICARE Manual Chap. 8 § 5.1(II)(B) ("If the device is used for a noncovered or excluded indication, benefits may not be allowed."); HGSAdministrators Coverage Determination L4672 (limiting coverage for cardiac ablation procedures to patients who are

"drug resistant, drug intolerant, or who have a contraindication to antiarrhythmic drugs"). To the extent that a healthcare provider seeks reimbursement for a cardiac ablation procedure that is ineligible for payment under a federal healthcare program – either because the program bars coverage for the off-label use of a medical device or because the program places other conditions on coverage that were not satisfied – the claim is false.[2] At a minimum, whether a federal healthcare program would pay for a procedure involving a particular off-label use of a medical device is a factual issue inappropriate for determination in a motion to dismiss.

Defendants also suggest that if a procedure code encompasses a particular procedure, federal healthcare programs must pay for that procedure. Brief at 18-19. But coding is separate and distinct from coverage. Whereas coding relates to classification of procedures, coverage relates to the determination as to whether such a procedure is reasonable and necessary. Thus, the fact that a new service or procedure has been issued a code does not, in itself, make the procedure medically reasonable and necessary or guarantee coverage under federal healthcare programs. See Svidler, 2004 WL 2005781, at *6 (rejecting argument that approval of billing code estops healthcare program from denying coverage).

Finally, a claim may be false for any number of reasons regardless of whether the federal healthcare program otherwise affords coverage for the particular procedure. For example, a claim may be false if it is miscoded. Likewise, a claim may also be ineligible for payment if a physician submitted a claim for reimbursement for which he received a kickback in exchange for prescribing a particular drug. See United States ex rel. Franklin v. Parke-Davis, 2003 WL 22048255, at *7 (D. Mass. Aug. 22, 2003); United States ex rel. Thompson v. Columbia/HCA Healthcare Corp., 20 F. Supp. 2d 1017, 1047 (S.D. Tex. 1998) (noting that government

[2] Defendants also argue that the use of a drug or device for an off-label indication is never material to the government's coverage determination. Defs. Brief at 19 (citing Polansky v. Pfizer, 2009 WL 1456582, at *7 (E.D.N.Y. May 22, 2009)). However, in Polansky, the Court narrowly considered only whether federal healthcare claims contain an implied certification that no drug was used off-label. Id. at *7. Because federal healthcare programs cover some off-label indications and not others, the primary inquiry is whether a particular off-label indication is covered, not merely whether that indication is off-label. If a program bars coverage for a particular off-label indication, the fact that a drug or device was used for that off-label indication is material to the program's decision to pay.

healthcare programs condition payment on provider's certification of compliance with relevant healthcare laws, including anti-kickback statute). This conclusion is supported by sound policy, as well as sound law. When a doctor prescribes a medical device or drug for a patient, the patient has a right to expect that the doctor's recommendation is based solely on his/her medical judgment of what is in the patient's best interests. But, when a company pays kickbacks to a doctor in order to induce him/her to use the company's products, it fundamentally compromises the integrity of this doctor-patient relationship. Moreover, illicit kickbacks can induce doctors to recommend surgery (even when surgery would not be the best option) or use devices or drugs that are inferior to competing products (or may be less well suited to particular patients), which in turn causes the quality of patient care to suffer. Additionally, when kickbacks induce doctors to opt for more costly treatments, or to prescribe more products or services than they otherwise would, health care costs are inflated, and, if federal health program beneficiaries are involved, taxpayer money is wasted. Federal healthcare programs rely on physicians to decide what treatment is appropriate and medically necessary for patients, and, therefore, payable by those federal programs. As a condition of its reimbursement, federal healthcare programs require that the physicians must render their services without the conflict of receipt of a kickback. Because compliance with the AKS is a condition of payment, a claim tainted by a kickback is false. Thus, the mere fact that a particular use is eligible for coverage under a particular federal healthcare program does not eliminate the possibility of fraudulent conduct or abuse that could render the claim false and ineligible for payment.

III. The FCA Does Not Require Proof of a "Double Falsehood."

Defendants assert that a device manufacturer's promotion of a device for an off-label indication cannot support an FCA claim unless the manufacturer made fraudulent misrepresentations to a healthcare provider. Thus, defendants argue that the FCA requires proof that a defendant made or caused both false statements and a false claim. However, their argument overlooks the fact that the first two sections of the FCA are distinct. Compare 31 U.S.C. § 3729(a)(1) and (a)(1)(B) (formerly (a)(2)). Liability under Section 3729(a)(1) does not

require proof that a defendant made a false statement; it requires only proof that the defendant presented or caused the presentment of a false claim. See United States ex rel. Wilkins v. N. Am. Const. Corp., 173 F. Supp. 2d 601, 620-21 (S.D. Tex. 2001) ("Subsection 3729(a)(1) of the False Claims Act does not contain the term 'false statement.' Rather, it requires a 'false or fraudulent claim' as the basis for liability."); Parke-Davis, 2003 WL 22048255, at *1 ("While § 3729(a)(2) contains a double-falsehood requirement . . ., there is no double falsehood requirement under § 3729(a)(1): One will suffice."); Rost, 507 F.3d at 731-33 (separately analyzing false statement allegations under Section 3729(a)(2)). To the extent that United States ex rel. Hess v. Sanofi-Synthelabo, 2006 WL 1064127 (E.D. Mo. 21, 2006) suggests that liability under Section 3729(a)(1) requires proof of both a false statement and a false claim, it is inconsistent with the text of the statute and wrongly decided.

Moreover, with respect to Section 3729(a)(1)(B), defendants appear to contend that the false statement requirement cannot be satisfied by showing that a defendant promoted a device for an off-label use. Defs. Brief at 11. As courts have long held both in the FCA context and otherwise, for a statement to be "false," it need not be an affirmative misrepresentation; a material omission will suffice: "[H]alf the truth may obviously amount to a lie, if it is understood to be the whole." W. Page Keeton, Prosser & Keeton on the Law of Torts § 106, at 738 (5th ed. 1984); see Luckey v. Baxter Healthcare Corp., 183 F.3d 730, 732 (7th Cir. 1999) (observing that a half-truth may amount to a false statement under the FCA in certain circumstances); United States ex rel. Schwedt v. Planning Research Corp., 59 F.3d 196, 199 (D.C. Cir. 1995) (finding that false progress reports may constitute false statements under the FCA); United States ex rel. Fry v. Guidant Corp., 2006 WL 2633740, at *10-11 (M.D. Tenn. Sept. 3, 2006) (finding representation was rendered false by concealment of material information); United States ex rel. Kneepkins v. Gambro Healthcare, Inc., 115 F. Supp. 2d 35, 43 (D. Mass. 2000) (an "omitted material fact," such as the existence of illegal kickbacks, may be actionable under the FCA). Thus, a statement urging a physician to use a device for an off-label use could well amount to a half truth and satisfy the false statement requirement of section

(a)(1)(B), where, for example, the device sales representative fails to mention that the evidence does not support the device's efficacy for the use he or she is promoting, the FDA has specifically concluded that the device is not effective for that use, or there are significant, undisclosed side effects that make the device not safe for that use.[3]

IV. Causation and Materiality under the FCA

Defendants argue that relator cannot establish causation because it would be unforeseeable for a doctor to rely on any advice, information, or recommendation from a device manufacturer regarding the practice of medicine. Defs. Brief at 22. However, courts have held that the actions of healthcare professionals are not an intervening force that breaks the chain of legal causation: "[T]he participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud." Parke-Davis, 2003 WL 22048255, at *2 ("Relator has presented evidence showing that it was foreseeable that Parke-Davis's conduct (including non-fraudulent promotion of off-label Neurontin uses) would ineluctably result in false Medicaid claims."); see also Allison Engine Co. v. United States ex rel. Sanders, 553 U.S. 662 (2008) (noting that a defendant is responsible for the "natural, ordinary and reasonable consequences of his conduct"). Indeed, the medical device industry would not employ the army of sales representatives who promote their products if these sales efforts had no effect on physician practices.

Defendants also contend that because hospitals bill the government based upon a diagnostic reimbursement code ("DRG") that is determined by the disease or procedure and not

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[3] Defendants suggest that the off-label marketing of an ablation device with clearance for a general intended use is a regulatory "gray area." However, FDA has issued guidance for the medical device industry regarding general and specific intended uses of medical devices. See FDA Center for Devices and Radiological Health, Guidance for Industry: General/Specific Intended Use (Nov. 4, 1998). Moreover, FDA has issued multiple warning letters to medical device manufacturers – including St. Jude and Boston Scientific – stating that when an ablation device is cleared only to ablate soft tissue, the manufacturer may not market the device for the treatment of a specific medical condition not identified on their label, including the treatment of atrial fibrillation. See, e.g., Warning Letter from T. Ulatowski to J. Song dated April 23, 2010 (http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm211596.htm); Warning Letter from L. Gill to R. Behl dated May 14, 1998 (http://www.fda.gov/downloads/ICECI/EnforcementActions/WarningLetters/1998/UCM066492.pdf).

by any particular medical device used in the procedure, there can be no false claim premised on defendants' conduct relating to the devices, even if the conduct was unlawful. The mechanics of reimbursement, however, do not insulate Boston Scientific from liability. To the extent that a federal healthcare program bars or limits eligibility for a procedure involving the manufacturer's device, and the manufacturer's practices cause a provider to submit a claim for that procedure, it does not matter how the government sets the reimbursement amount – whether by DRG or otherwise – the claim is false regardless. See generally United States ex rel. Main v. Oakland City Univ., 426 F.3d 914, 916 (7th Cir. 2005) ("If a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork."). Thus, if a device is not covered – either because the procedure is not reasonable and necessary or because the claim is tainted by kickbacks – federal healthcare programs do not pay for the procedure.[4]

[4] The cases that Defendants cite in support of their assertion regarding DRG reimbursement are inapposite. As a preliminary matter, most of those cases do not involve off-label medical devices. See United States ex rel. DiGiovanni v. St. Joseph's/Candler Health System, Inc. 2008 WL 395012 (S.D. Ga. Feb. 8, 2008) (alleging improper billing practices); United States ex rel. Kennedy v. Aventis Pharms, 2008 WL 5211021 (N.D. Ill. Dec. 10, 2008) (alleging off-label use of drugs – not devices); Hess, 2006 WL 1064127 (same). In United States ex rel. Stephens v. Tissue Sci. Labs., Inc., 664 F. Supp. 2d 1310 (N.D. Ga. 2009), the Court held that although claims involving the off-label use of a surgical mesh device were false, the off-label use of the mesh device was not material to the program's payment decision because it was not the "sole or primary" service provided to the patient. Id. at 1318. Putting aside whether that limitation is correct, there is no question that, in this case, the off-label use of a surgical cardiac ablation device is the "sole or primary" service in a surgical cardiac ablation procedure for which physicians would seek coverage.

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Respectfully submitted,

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